

## REMARKS

The Office Action stated that it is noted that the preliminary amendment refers to a "new Abstract set out on a separate page" to be substituted for the original Abstract, however, it is noted that no "new Abstract" was submitted with the amendment. The applicants submit herewith the new Abstract on the attached separate page.

Claims 11 to 29 have been cancelled and new Claims 30 to 48 have been inserted.

Claims 11 to 27 have been rejected under 35 U.S.C. 102(b) as being anticipated by Breitler et al. (U.S. Patent No. 5,589,275). Applicants traverse this rejection.

Applicants' invention involves a sterilizable composite film containing a barrier layer that is impermeable to water vapor and gases comprising a metal foil and on both sides of the barrier layer at least one functional layer. The invention sterilizable composite film has a simple structure, withstands the sterilization conditions without delamination, and can be easily processed into pouches. The composite film has a layer structure containing one on top of the other:

(a) a first functional layer containing a first plastic film that is a polyolefin or an extrusion layer of a polyolefin or one or more lacquer layers, or print and lacquer layers, or print layers;

(b) a metal foil, the first plastic film is (i) in direct contact with the metal foil or (ii) in direct contact with a layer of a bonding agent that is in direct contact with

the metal foil or (iii) in direct contact with a layer of a laminate adhesive that is in direct contact with the metal foil; and

(c) a second functional layer that is a second plastic film comprising a film of (i) a plastic consisting of coextruded polyamide layer/polypropylene layer where the polyamide layer is in direct contact with the polypropylene layer, and (ii) optionally at least one suitable or conventional plastic system additive in plastic (i), the polyamide lies between the metal foil and the polypropylene layer, the coextruded polyamide layer/polypropylene has a bond sufficient to prevent delamination thereof during sterilization.

Breitler et al. does not teach or suggest applicants' claimed composite.

Anticipation under Section 102 requires that a prior art reference disclose all of the features, limitations, structures, etc., recited in a claim. Breitler et al. discloses a polyamide layer on each side of the metal foil. Breitler et al. does not disclose any member of applicants' first functional layer between either of its polyamide layers and its metal layer, therefore Breitler et al. does not teach or suggest applicants' composite film.

The Office Action stated: that Breitler et al. teaches a composite material containing a metal layer, on both sides of that is a plastic layer wherein the metal layer is metal foil, preferable aluminum or aluminum alloy with an aluminum purity of most preferable 99.5 percent or higher, including AA8014, AA8079, or AA8101, having a thickness of 8 to 120  $\mu\text{m}$ ; and that wherein the plastic layer(s) is a polyamide-based thermoplastic containing polyamide with a thickness of 20 to 50  $\mu\text{m}$  (Abstract; col. 1, lines 19 and 20; and col. 3, lines 1 to

22 and lines 66 and 67). Applicants traverse this statement as being an incorrect statement of the disclosure of Breitler et al. As per the disclosure of Breitler et al., the only layers that can be between the polyamide layers and the metal layer are thin adhesive layers and/or thin primer or bonding agent layers and/or barrier layers.

Breitler et al. works with a basic composite material of a metal layer with a polyamide layer on both sides. When Breitler et al. permits any layer (i.e., adhesive or bonding agent or primer) between one of the polyamide layers and the metal layer, Breitler et al. specifically indicates such. All of the other layers mentioned by Breitler et al. are located outside of the polyamide layers (i.e., not between the polyamide layers and the metal layer). Breitler et al. does not disclose any polyolefin layer between either of its polyamide layers and its metal layer.

Breitler et al. uses polypropylene in sealing layers located on the outside of the polyamide layers. Sealing layers are not used by Breitler et al. inside of the polyamide layers.

The Office Action stated that Breitler et al. teaches that the plastic layers on both sides of the metal layer include composites of two or more films or layers wherein the polyamide-based thermoplastic layers may additionally and independent of each other be provided with an outer lying sealable layer and/or barrier layer of thermoplastics, such as, a polypropylene sealable layer, wherein the sealable layers are sealable films deposited via adhesives, applied by lamination or lamination coating wherein the thickness of the sealable films may

be 6 to 100  $\mu\text{m}$  thick and furthermore, one or more layers, e.g., 1 to 10  $\mu\text{m}$  thick, of a sealing layer coating may be deposited on the plastic composite (col. 4, lines 1 to 38). Applicants traverse this statement as it does not indicate that there is no disclosure in Breitler et al. that places any sealable layer between the polyamide layers and the metal layer.

The sealable layers of Breitler et al. only lie outside of the polyamide layers.

The Office Action stated that Breitler et al. further teaches that a single or double-sided sealable composite may be obtained by single or double-sided coextrusion of the plastic layers, wherein in that connection, it is useful for the plastic layers to contain or comprise a polyamide-based thermoplastic and at least one polyamide layer to feature a sealing layer on at least one side, i.e., each layer of polyamide thermoplastic may be covered with a sealable layer on one side or both sides, independent of the other layers (col. 4, lines 36 to 45). Applicants traverse this statement as being clearly incorrect.

The issue is whether Breitler et al., in column 4, lines 9 to 44, particularly lines 36 to 44, discloses:

- (1) an outerlying sealable (polypropylene) layer on either or both sides of the composite material; or
- (2) a sealable (polypropylene) layer on either or both sides of each polyamide layer (of the composite).

Analysis of the disclosure of Breitler et al. clearly shows that column 4 thereof deals with an outerlying sealable layer on either or both sides of the composite material.

The Examiner's position that column 4 of Breitler et al. deals with the polyamide layers (instead of the composite material) is in error.

The Examiner has incorrectly taken portions of column 4 of Breitler et al. out of context and has misanalyzed such disclosure. The context of Breitler et al. is that Breitler et al. is dealing with the composite material.

Throughout all of Breitler et al. the context is the composite material of their invention. When Breitler et al. speaks of "on one or both sides". Breitler et al. is only speaking of the composite material.

The C.A.F.C. in Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc. 230 U.S.P.Q. 416, 119-420, (1986), stated:

"The court also engaged in improper hindsight analysis to conclude the '814 patent would have been obvious. \*\*\*."

"Barnes-Hind selected a single line out of the Caddell specification to support the above assertion: \*\*\*. This statement, however, was improperly taken out of context. As the former Court of Customs and Patent Appeals held:

It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such

reference fairly suggests to one skilled in the art.

*In re Wesslau*, 353 F.2d 238, 241, 147 USPQ 391,393 (CCPA 1965);  
*see also In re Mercer*, 515 F.2d 1161, 1165-66, 185 USPQ 774,778  
(CCPA 1975)."

"A full appreciation of Caddell's statement requires consideration of the immediately following sentences in the same paragraph and the paragraph after that. Viewed in that context, it is apparent that \*\*\*. \*\*\* A complete reading demonstrates quite clearly that \*\*\*. The district court improperly viewed an isolated line in Caddell in light of the teaching of the '814 patent to hold for obviousness. This is improper hindsight analysis."

"The district court also failed to consider the Caddell reference in its entirety \*\*\*. \*\*\*." [Emphasis supplied]

The C.A.F.C. in *In re Evanega et al.*, 4 USPQ 2d 1249, 1251, (1987), stated:

"When read together and in context, \*\*\*. \*\*\* Instead, the entirety of Schuurs suggests that \*\*\*. *See Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568, 1 USPQ 2d 1593, 1597, *cert. denied*, 107 S.Ct. 2187 (1987) (in determining obviousness, a prior patent must be considered in its entirety). Thus, we conclude that the board erred in determining that Schuurs established a prima facie case."

The context of all the disclosure of Breitler et al. is the composite material of their invention. Breitler et al., for example states:

"The invention relates to a metal-plastic composite material \*\*\*." [Emphasis supplied] [Col. 1, lines 6 and 7]

"The object of the present invention is to provide a metal-plastic composite material \*\*\*." [Emphasis supplied]  
[Col. 2, lines 25 and 26]

"The objective is achieved by way of the invention in the form of a \*\*\* composite material \*\*\*." [Emphasis supplied]  
[Col. 2, lines 29 to 31]

"The composite material \*\*\*." [Abstract, first line]

The portion of column 4 of Breitler et al. relied upon by the Patent Office clearly deals with sealable layers located on the outer sides of the composite material. The context is entirely in terms of the composite material. There is no teaching of a sealing layer between a polyamide layer and the metal layer in the text in lines 3 to 45 of column 4 of Breitler et al., which reads as follows:

"The plastic layers on both sides of the metal layer of the composite according to the invention \*\*\*."

"The plastic layers on both sides of the metal layer, in particular the polyamide-based thermoplastics may additionally, and independent of each other, be provided with an outer lying sealable layer and/or a barrier layer of thermoplastics."

"The composite according to the invention may also feature a sealing layer or sealable layer on one or both sides."

"The composite material according to the present invention forms a composite containing plastic film that, in order to extend the range of

properties, may be coated with one or more layers of material such as e.g. plastic films."

"Sealable layers are e.g. sealable films deposited e.g. via adhesives that contain or are free of solvents, or water-based adhesive systems, applied by extrusion lamination or lamination coating. Sealable films may contain or consist of e.g. LLDPE, LDPE, MDPE, HDPE, polypropylene, polyethylene-terephthalate or polyolefin-based isomers. Ionomers or ionomer-containing polymers with typical properties of ionomers may be thermoplastic copolymers of olefin with carboxyl-containing monomers, a part of which are present as free carboxyl groups and the remainder bonded to metal cations so that some transverse cross-linking is achieved. Polyethylene-based ionomers are known under the trade name Surlyn. Sealable films may be 6 to 100  $\mu\text{m}$ . Furthermore, one or more layers e.g. 1 to 10  $\mu\text{m}$  thick, of a sealing coating or hot-sealing coating, for example, may be deposited on the plastic film composite."

"A single or double-sided sealable composite is obtained by single or double-sided coextrusion of the plastic layers with e.g. a polypropylene/polyethylene copolymer."

"In that connection it is useful for the plastic layers to contain or comprise of a polyamide-based thermoplastic and at least one a polyamide-based thermoplastic to feature a sealing layer on at least one side i.e. each layer of polyamide-based thermoplastic may be covered



with a sealable layer on one or both sides, independent of the other layers.” [Emphasis supplied]

All references to sealing layers in such text are exclusively to sealing layers, located on the outer surfaces of the composite material, i.e., on the outer surface of the plastic layers of the composite material.

Lines 36 to 45 of column 4 of Breitler et al. recites “\*\*\* with a sealable layer on one or both sides, \*\*\*” This statement refers to the sides of the composite material (and not to the polyamide layers) as shown by the language of lines 36 and 39 and the overall context of usage in Breitler et al. This is further confirmed by usage of such language elsewhere in Breitler et al.

Breitler et al., in column 5, line 49, to column 6, line 14, states:

“Typical arrangements of the layers in composites according to the invention include for example:

- a) a middle layer of aluminium of thickness e.g. 8 to 80  $\mu\text{m}$ , preferably 40 to 70  $\mu\text{m}$  and in particular 45 to 60  $\mu\text{m}$ , and on each side of the aluminum layer
- b) and b') a layer of adhesive coating and/or bonding agent having a thickness of 1.5 to 9  $\mu\text{m}$ , or 1 to 10  $\text{g}/\text{m}^2$
- c) and c') a layer of a biaxially stretched polyamide of thickness e.g. 20 to 50  $\mu\text{m}$ , preferably 20 to 40  $\mu\text{m}$  and in particular 20 to 30  $\mu\text{m}$

and if desired

- d) and d') a barrier layer on one or both sides

and if desired

e) and/or e') a layer of a sealing coating or sealing layer on one or both sides in a quantity of 2 to 6 g/m<sup>2</sup>, or of thickness up to 10 µm."

\* \* \*

"Useful composite materials contain \*\*\*. \*\*\* Analogously, layers b), c), d) and e) are provided on one side of layer a) and layers b'), c'), d') and e') on the other side of layer a)." [Emphasis supplied]

Page 2100-120 of the M.P.E.P. states that a "prior art reference must be considered in its entirety, i.e., as a whole, \*\*\*." It is error for the Patent Office to take a sentence(s) out of context, particularly where such sentence(s), as here, refer to other sentences/paragraphs that clearly establish the context.

Lines 9 to 13 of column 4 of Breitler et al. states:

"The plastic layers on both sides of the metal layer, in particular the polyamide-based thermoplastics may additionally, and independent of each other, be provided with an outer lying sealable layer and/or a barrier layer of thermoplastics." [Emphasis supplied]

Such text is not discussing the plastic layers by themselves but instead only as components in the structure of the basic composite material. The use of the phrase "outer lying sealable layer" refers only to the outside surfaces of the basic composite material (i.e., the outside surface of each of the plastic layers). The words "outer lying" refer only to the side of each of the plastic layers away from

the metal foil. Furthermore, the above quotation also shows that the sealable layers were only located on the outside of the composite material on the outer side of the polyamide layers.

The phrase "on outer lying sealable layer and/or a barrier layer" restricts the sealable layer to the outside surface of the plastic layers in the composite material. The term "outer lying" does not modify the barrier layer.

When Breitler et al. meant that a substance or layer could be located between a plastic layer and the metal layer, the text clearly says or indicates so. Column 4, lines 46 to 61, of Breitler et al. states:

"Beside the metal foil, at least one additional layer may be provided as a barrier layer \*\*\*. \*\*\* Barrier layers are situated for example between the metal layer and the polyamide layer or layers; the barrier layers are preferably situated on the polyamide layer on the opposite side facing the metal layer. Foreseen in particular is a barrier layer on one side of the metal layer only, lying on the polyamide layer."

The above quotation recites that the barrier layer can be between one of the plastic layers and the metal foil. The term "outer lying" does not modify "a barrier layer", but instead restricts the location of the "sealable layer" to the outside surface of the plastic layer away from the metal foil.

During the examination of Breitler et al., the Patent Office cited U.S. Patent No. 5,100,708 (Heyes et al.) against their underlying application.

Heyes et al. disclosed a laminated metal sheet where the metal sheet had on one of its (major) surfaces a composite of an inner layer (A<sup>1</sup>) of thermoplastic polymer and an outer layer (B<sup>1</sup>) of thermoplastic polymer. Page 3 of the Office Action of March 5, 1996 therein stated: "The thickness of the inner and outer layer of the thermoplastic polymer \*\*\*." The Patent Office clearly was aware of that which was meant by "outer" or "outer laying" in the Breitler et al. application. Page 3 of the Amendment of October 13, 1995 stated: "In Heyes et al., the wording 'inner' means between the metal layer and the outer layer. Both the inner and outer layers are arranged on the same side of the metal sheet." The prosecution/examination history of Breitler clearly shows that the terms "outer" and "outer lying" do not mean between the metal foil and a polyamide layer.

There is no reason in the composite material of Breitler et al. to have an inner sealable layer (it already typically has an adhesive coating and/or bonding agent between the metal foil and the polyamide layer). The sealing layer of Breitler et al. is used only as the outermost layer for the purpose of safely fixing or sealing the lid to the base part of a packaging. The Examiner did not correctly analyze column 4 of Breitler et al. in view of such reference as a whole.

The Office Action stated that Breitler et al. teaches that to join the aluminum foil or to bond the plastic films or individual layers to each other, an adhesive coating and/or bonding primer are usually employed wherein a suitable adhesive is a maleic-anhydride modified polypropylene, and suitable bonding agents are epoxy or urethanes, wherein the bonding agent or primer may be, for

example, applied in amounts of 0.1 to 10 g/m<sup>2</sup>, usefully 0.8 to 6 g/m<sup>2</sup> or the adhesive layer has a thickness of 1 to 12 µm or applied in an amount of 0.1 to 14 g/m<sup>2</sup> (col. 5, lines 3 to 47). This disclosure of Breitler et al. does not anticipate applicants' overall claimed invention.

The Office Action stated that Breitler et al. further teaches that the composite material may also feature a sealing layer such as PET on one or both sides of the composite independent of the other layers, with a thickness of 6 to 100 µm (Col. 4, lines 20 to 35). It is not a further teaching, it is the only teaching of Breitler et al. regarding the sealing layers.

The Office Action stated that Breitler et al. teaches a number of layer arrangements including the layer structure as instantly claimed wherein the plastic films may be formed by warm coating or coextrusion and may be subjected to stretch-drawing, to produce a composite film useful in manufacturing packaging and parts of packaging such as packaging containers, base parts, blister packs, for storing or packaging foodstuffs or pharmaceutical products (col. 5, line 48, to col. 6, line 23; and col. 6, line 65, to col. 7, line 33). Applicants traverse this statement. As shown above, Breitler et al, does not teach the structural sequence of applicants' layers. Breitler et al. does not anticipate applicants' claimed invention.

The Office Action stated that, with regards to the limitation "lacquer", the Examiner takes the position that the synthetic coating layers taught by Breitler et al. reads on the term "lacquer" layer. Even if so, Breitler et al. does not teach or suggest applicants' claimed invention.

The rejection should be withdrawn.

Claims 11 to 27 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Breitler et al. in view of *Ullmann's Encyclopedia of Industrial Chemistry*, vol. A11, (Ullmann). Applicants traverse this rejection.

The Office Action stated that the teachings of Breitler et al. are discussed above. Breitler et al., as shown above, does not teach or suggest applicants' claimed invention. Ullmann does not cure any of the defects of Breitler et al. in the search for applicants' claimed invention.

Breitler et al., for example, states:

"The composite material contains a metal layer on both sides of which is a plastic layer; \*\*\*; the plastic layers contain or comprise polyamide-based thermoplastics." [Abstract]

Breitler et al. does not teach or suggest the layer structure of applicants' claimed invention, as applicants demonstrated under the above anticipation rejection.

The Office Action stated that Breitler et al. teaches a composite film containing a metal foil, particularly aluminum, with plastic films on both sides thereof wherein the plastic films may be multiplayer films formed from various layer structures and specifically teach the general layer structure as instantly claimed with layer thickness within or comprising the instantly claimed ranges utilizing optional adhesive, bonding and/or primer layers to bond plastic layers to each other and/or to the metal foil as instantly claimed wherein the plastic films may be extruded, coextruded, or laminated via adhesive. Applicants traverse this statement as an unjustified attempt to generify the limited disclosure of

Breitler et al. The plastic films of Breitler et al. contain or comprise polyamide-based thermoplastics. Breitler et al. does not disclose applicants' claimed first functional layer and its structural relationship with the metal foil and does not include applicants' claimed first functional layer between a polyamide layer and the metal foil (layer).

The Office Action stated that, though Breitler et al. discloses all of the layers, layer materials and layer thickness as instantly claimed, Breitler et al. does not specifically limit the invention to the specific composite film combination as instantly claimed, however, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize any of the structures disclosed by Breitler et al. selecting from the disclosed materials taught by Breitler et al. based on the desired film properties for a particular end use, and further to utilize routine experimentation to determine the optimum thickness of the individual layers given that layer thickness is a result-effective variable affecting the barrier, mechanical, adhesion and sealing properties of the resulting composite based on the desired end use of the packaging composite taught by Breitler et al. Applicants traverse this statement as being hindsight and speculation. Furthermore, Breitler et al. does not teach or suggest the layer structure claimed by applicants.

The Office Action stated that, further, it would have been obvious to one having ordinary skill in the art to determine the appropriate laminating method, such as, extrusion laminating, lamination coating, coextrusion or laminating via adhesives as taught by Breitler et al., to produce the multiplayer plastic films

based on the individual layer materials to be laminated wherein laminating via adhesives, extrusion coating and coextrusion are conventional methods of producing composite plastic films as evidenced by Ullmann which specifically teach that coextrusion is unique in that it can produce very thin multiplayer films and that polyamide films are mainly employed in composite structures produced by lamination, extrusion coating, or coextrusion with sealing or barrier resins (6.7 Polyamide, page 105). This statement is, of course, hindsight. But, even further, the combination of Breitler et al. and Ullmann still does not result in the layer structure claimed by applicants.

The Office Action stated that Ullman also teaches that composite films are conventionally utilized in the packaging industry to produce various packaging structures such as bags, sacks, and blister or cushion packs, or thermoformed structures such as containers from thicker films, wherein the combination of plastic films with aluminum foil produces semirigid composites with exceptionally low permeability to gases, water vapor and odors (6.13 Composite Films, 7. Summary of Uses, pages 108 and 109). This statement does not supply the claimed layer structure.

This rejection should be withdrawn.

Claim 28 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Breitler et al. Applicants traverse this statement.

Breitler et al. does not teach or suggest applicants' claimed structure, so Claim 28 is clearly unobvious.



The Office Action stated that, though Breitler et al. teaches that the composite film may be provided with a sealing or sealable layer on either or both sides such as PET or like materials, Breitler et al. does not teach the use of PBT, however PBT is a known functional equivalent to PET and it would have been obvious to one having ordinary skill in the art at the time of the invention to substitute PBT for PET given that they are functional equivalents. Applicants traverse this statement. Breitler et al. disclose applicants' claimed layer structure.

This rejection should be withdrawn.

Claim 29 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Breitler et al. in view of Abrams (U.S. Patent No. 6,090,471). Applicants traverse this rejection.

Breitler et al. does not teach or suggest applicants' claimed structure, so Claim 29 is unobvious. Abrams does not cure the defects of Breitler et al. in the quest for applicants' claimed invention.

The Office Action stated: that, though Breitler et al. teaches that the composite is useful for producing packaging materials, Breitler et al. does not teach that the composite further comprises a print layer or a print layer with a lacquer overcoat on the polyester outer layer; that, however, it is well known in the art, as taught by Abrams, that a sterilizable packaging composite can comprise a print layer to provide desired product information for a particular packaging end use and that a protective overcoat or lacquer layer can be provided over the print layer to protect the print layer during sterilization; and that,

therefore, one having ordinary skill in the art at the time of the invention would have been motivated to include a print layer on the composite taught by Breitler et al. to provide desired product information or decorative properties, wherein the print layer is further provided with a protective overcoat layer during sterilization as taught by Abrams. Applicants traverse this statement since it is mere forbidden hindsight and is an unjustified attempt to generify the specific disclosure of Breitler et al. The rejection combination does not result in applicants' claimed layer structure.

This rejection should be withdrawn.

Claims 11 to 29 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 38 to 54 of copending Application No. 09/505,713 in view of Breitler et al. (U.S. Patent No. 5,589,275) or EP 0 845 350 (EP '350). Application No. 09/505,713 was abandoned on in favor of Application No. 10/083,110 so it is assumed that the Examiner meant the latter application. A terminal disclaimer and the terminal disclaimer fee are separately submitted.

This provisional rejection should be withdrawn. Reconsideration, reexamination and allowance of the claims are requested.

Respectfully submitted,

Jan. 30, 2003  
Date

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

Claims 17 to 29 have been cancelled.

New Claims 30 to 48 have been inserted.